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(56) Documents Cited

EP 0619982 A2	EP 0611557 A2	WO 95/22930 A1
US 5443482 A	US 5417712 A	US 5411506 A
US 5372604 A	US 5207679 A	US 5152790 A
US 4970957 A		

(58) Field of Search
UK CL (Edition O) A5R RAM RESA
INT CL[6] A61B 17/03 , A61F 2/08

(54) **A surgical anchor and installation tool**

(57) A surgical anchor 10 for anchoring a prosthetic or soft tissue graft (34) in a blind bone tunnel, comprises an anchoring means 18, preferably threaded, and a retaining means 14, preferably eye shaped, for retaining the prosthetic or soft tissue graft (34). The anchor may have a recess 20 in the nose end to accommodate a guide wire. A tool (50) for fixing the anchor into a bone tunnel comprises a hollow shaft (52) (to accommodate a ligature), a head (56) and a handle (54). The head is constructed of two longitudinally shaped tongues which form a wedge to engage the retaining means of the anchor.

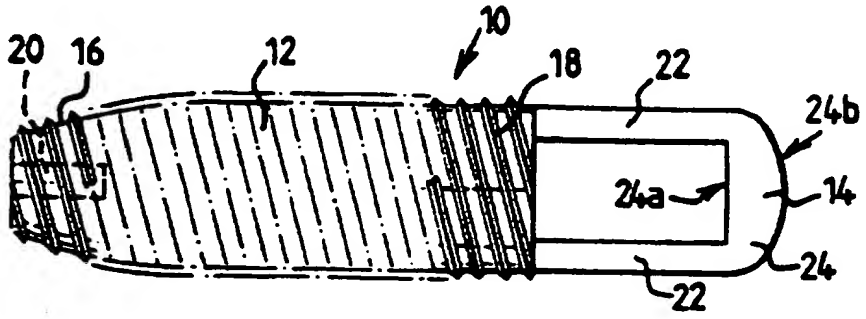

FIG. 1

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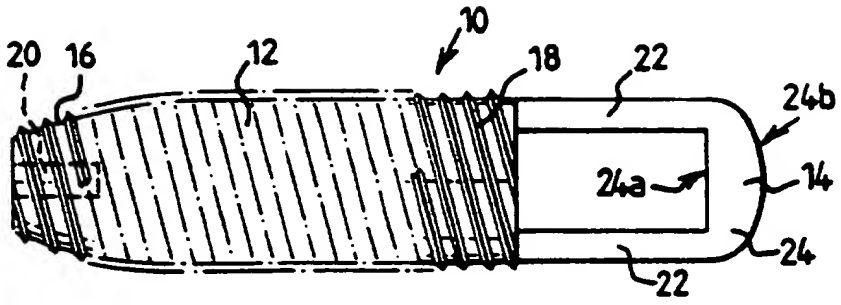

FIG. 1

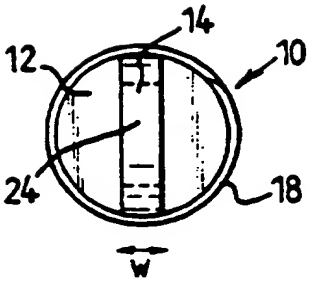

FIG. 2

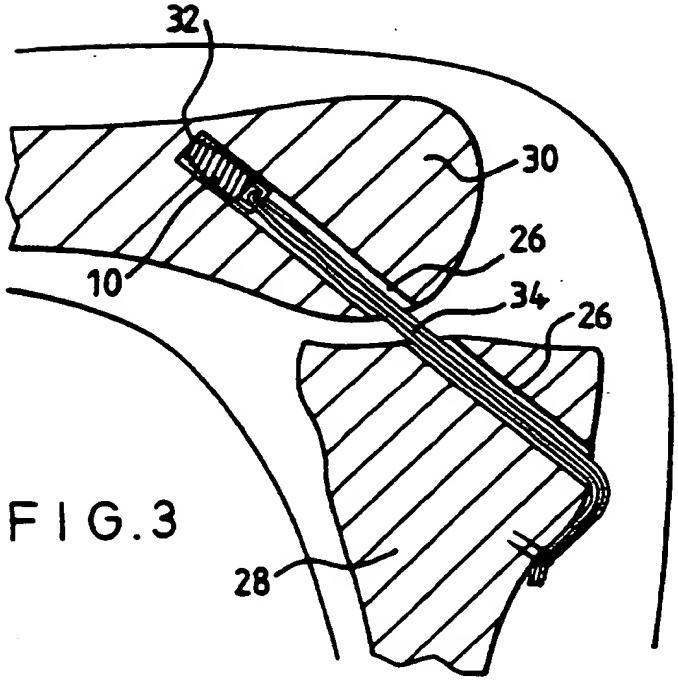

FIG. 3

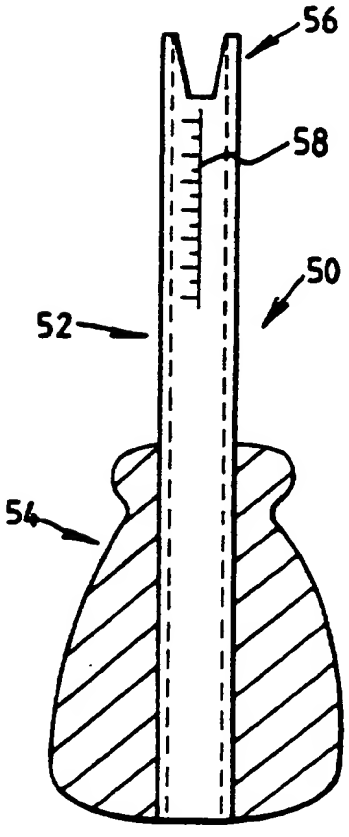

FIG. 4

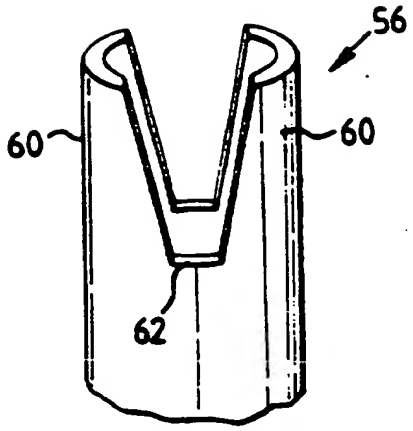

FIG.5

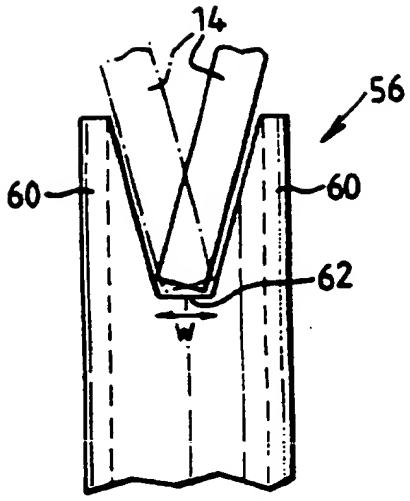

FIG.6

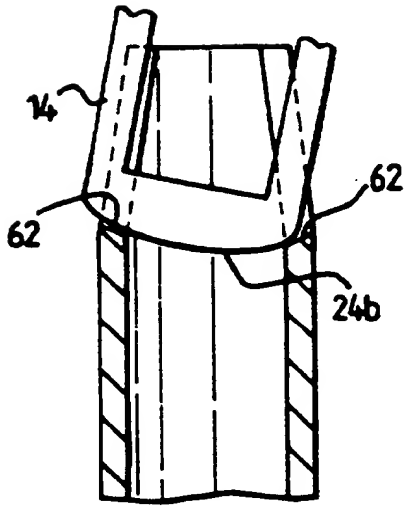

FIG.7

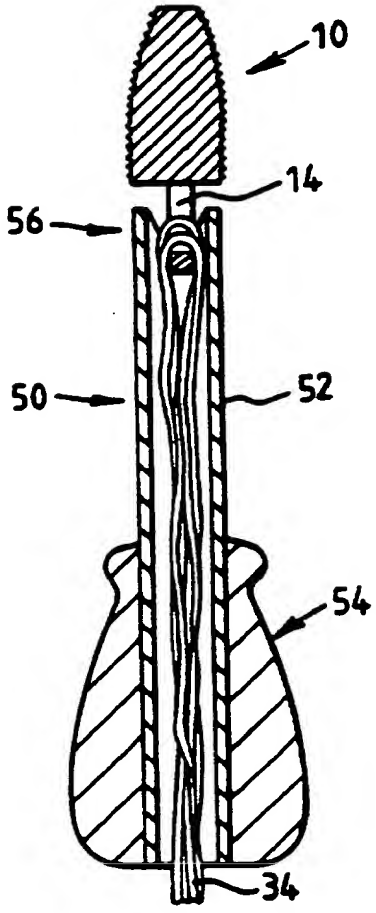

FIG.8

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A Surgical Anchor and a Tool for Fixing Same

The invention relates to a surgical anchor, particularly but not exclusively to a surgical anchor for anchoring ligaments within a bone tunnel.

Injuries or repairs to a knee joint can involve damage to one or both cruciate ligaments which provide anterior-posterior stability in the knee joint. When such damage occurs, a common method of repair involves utilising an auxiliary ligament (prosthetic or soft tissue graft) which can be taken from the Achilles tendon, hamstring or other suitable area. The auxiliary ligament can be placed alongside the damaged ligament whilst natural healing takes place or can replace a ligament which has been removed. In either case, a tunnel is formed in the proximal head of the tibia and the distal head of the femur. The auxiliary ligament is then passed through the tunnel from the tibial end, slipped through an anchoring washer or other fastener and returned along the tunnel. The ligament is then held by the washer at the femoral end and stapled or fixed in other known manner at the tibial end. Often, the anchoring washer is arranged to project into the tunnel from the surface of the femur so as to allow an adequate length of ligament to protrude beyond the surface of the tibia for fixation purposes.

A major problem with this type of damage repair is that the resultant scarring can be severe, particularly above the knee joint. It is therefore desirable to reduce or eliminate the scarring produced by an operation of this type. It has been suggested (European Patent Application No. 0 496 140 A) that a ligament anchor can be introduced into the bone tunnel from the tibial end and passed, with the auxiliary ligament attached, to the femoral end where a hook portion, previously resiliently retracted, extends beyond the mouth of the tunnel and prevents the anchor from being pulled back into the tunnel. The anchor is then securely held at the femoral end of the tunnel when tension is applied to the auxilliary ligament. However, the anchor is then

wholly dependent upon a small area of the mouth of the bone tunnel at the femoral end thereof for its adequate operation. If the tunnel is drilled wholly from the tibial end, the femoral mouth may be irregular or weakened, thereby reducing the reliability of operation of the anchor. If the bone tunnel is drilled at least partly from the femoral end, there is no reduction in the amount of scarring resulting from the operation. It is also difficult to drill a tunnel right through the femoral head from the tibial end without causing some damage to the tissue surrounding the femur.

It is an object of the invention to provide a surgical anchor for anchoring ligaments in a bone tunnel which will allow the amount of scarring produced by the operation to be reduced. It is a further object of the invention to provide a surgical anchor for anchoring ligaments in a bone tunnel which can be placed in position via a single entrance to the bone tunnel. A further object of the invention is to provide a tool for facilitating the placing of a surgical anchor of the aforementioned type.

The invention provides a surgical anchor as claimed in Claim 1. Further and advantageous features are set out in subsidiary Claims 2 to 10.

The invention also provides a tool as claimed in Claim 11. Further and advantageous features are set out in Claims 12 to 22.

An embodiment of the invention will now be described with reference to the accompanying drawing, wherein:

Figure 1 is a side view of a surgical anchor according to the invention;

Figure 2 is an end view of the surgical anchor of Figure 1;

Figure 3 is a schematic diagram illustrating the use of the anchor of Figure 1;

Figure 4 is a schematic side view of a tool according to the invention;

Figure 5 is an enlarged perspective view of the head of the shaft of the tool of Figure 4;

Figures 6 and 7 illustrate the cooperation of a surgical anchor and the head of the tool of Figure 4; and

Figure 8 is a sectional view of a combination of a surgical anchor and tool in use.

A surgical anchor according to the invention is illustrated in Figures 1 and 2. The surgical anchor 10 has a body portion 12 and retaining means 14. The body portion 12 is generally cylindrical in shape and has a rounded nose portion 16. The body portion 12 is therefore generally bullet-shaped. A screw thread 18 extends over the side walls of the body portion 12 from the nose portion 16 to the retaining means 14. The screw thread 18 is of the type commonly used in bone screws in order to ensure secure anchoring in a bone mass. A blind recess 20 is located centrally in the nose portion 16 of the body portion 12 and extends coaxially with the longitudinal axis of the body portion 12.

The retaining means 14 consists of an eye portion comprising two diametrically opposed arms 22 extending generally parallel to the longitudinal axis of the body portion 12. The eye portion 14 is closed by a laterally extending end portion 24 which joins the arms 22. The side 24a of the end portion 24 which faces the body portion 12 is substantially flat or planar whereas the side 24b remote from the body portion 12 is part-cylindrical in shape.

The surgical anchor described above is made from titanium, cobalt-chrome alloy, stainless steel or another implant-grade material. Its use will now be described with reference to Figure 3.

Figure 3 is a schematic side view of a knee joint following an operation to replace a cruciate ligament using a surgical anchor described above. A bone tunnel 26 is drilled using standard drilling apparatus and techniques through the proximal head of the tibia 28 and into the distal head of the femur 30. However, the bone tunnel 26 terminates before exiting the far side of the femur 30 so that a blind end 32 is created. However, the bone tunnel 26 extends at least as far as the outer cortex of the femur 30 beyond the central cancellous bone matter. The bone tunnel 26 does not extend as far as the outer surface of the femur 30.

An auxiliary ligament 34, formed by a prosthetic or soft tissue graft, is looped through the eye portion or retaining means 14 of the surgical anchor 10. The surgical anchor 10 is then introduced into the bone tunnel 26 and secured at the blind end 32 thereof by screwing. The auxiliary ligament 34 is then securely held at the blind end 32 of the bone tunnel 26 and extends back along the bone tunnel 26. The free ends of the auxiliary ligament 34 can be stapled to the exterior surface of the tibia 28 by known stapling means or other suitable fixation means after suitable tensioning is applied.

The surgical anchor described above has many advantages. Firstly, it can be readily introduced into a bone tunnel from the tibial end thereof which means that no surgical incisions are required above the knee joint. Residual scarring above the knee is thereby eliminated. If required, a guide wire can be inserted into the bone tunnel to ensure that the surgical anchor 10 follows the correct line but, even if this is required, only a very small incision in the patient's skin above the knee is necessary. The blind recess 20 in the nose portion 16 of the surgical anchor 10 is intended to receive a guide wire for the purpose of assisting the surgeon in placing the surgical anchor correctly.

The flat side 24a of the end portion 24 of the retaining means 14 ensures that the auxiliary ligament 34 remains evenly spread across the entire width of the end portion 24. It is important to spread the ligament 34 across as much of the bone tunnel 26 as possible and to ensure that the ligament 34 does not "bunch up" in the centre of the tunnel 26. This is because the ligament 34 is required to graft itself to the wall of the tunnel 26 which will then produce a permanent bond between the respective materials. Of course, the illustrated relative dimensions and overall shape of the retaining means 14 can be varied if required: it is envisaged that the retaining means 14 could take the shape of a "J" thereby leaving a gap in one of the arms 22 to facilitate introduction of the auxiliary ligament into the eye portion. Indeed, any shape suitable for retaining the auxiliary ligament in close proximity to the body portion 12 would be within the scope of this invention. It would also be within the scope of this invention to provide alternative anchoring means other than a screw thread for anchoring the body portion 12 in the blind end of the tunnel 26. Resilient teeth allowing the body portion 12 to

advance along the tunnel but preventing rearward movement may be sufficient The blind recess 20 can be dispensed with.

It will be appreciated that the introduction of the surgical anchor 10 described above into the bone tunnel 26 requires a considerable amount of care and skill. Indeed, it is envisaged that the introduction of the surgical anchor into the bone tunnel 26 will require use of a specially adapted tool designed for this purpose. An appropriate tool which will greatly assist in the introduction of the surgical anchor 10 into the blind end of the tunnel 26 is illustrated in Figures 4 to 8.

The tool 50 illustrated in Figures 4 to 8 has the appearance of a screwdriver. The tool 50 consists essentially of a shaft 52 and a handle 54. The shaft 52 extends all of the way through the handle 54, which is shaped so as to be easily gripped and rotated by the surgeon about the longitudinal access of the shaft 52.

The shaft 52 incorporates a head 56 at the end of the shaft 52 remote from the handle 54. Graduations 58 are arranged along the shaft 52 between the head 56 and the handle 54. The graduations 58 are standard graduations given in millimetres and adapted to indicate to the surgeon the depth of penetration of the head 56 into the bone tunnel.

The shaft 52 is open at the head 56 and is hollow along the entire length thereof. Because the shaft 52 extends through the handle 54, the shaft 52 is also open at the end remote from the head 56. The exterior diameter of the shaft 52 is a little smaller than the diameter of the bone tunnel into which the tool 50 is to be introduced so as to allow unhindered passage of the tool head 56 therealong. The outer diameter of the shaft 52 can be sufficiently small to allow a little play between the shaft 52 and the bone tunnel if required. The interior diameter of the shaft 52 is sufficiently large to allow an auxiliary ligament to extend therealong. In operations to replace cruciate ligaments, the auxiliary ligament is usually doubled over so as to provide adequate strength in the new

ligament. Therefore, the interior diameter of the shaft 52 must be capable of accommodating a doubled-over ligament of the type required.

It is not essential that the shaft 52 passes entirely through the handle 54. Indeed, the shaft 52 can extend only part way into the handle 54 in order to allow communication with an interior cavity formed within the handle 54. Alternatively or additionally, the interior cavity or shaft 52 can include means not shown for temporarily clamping an auxiliary ligament within the extremities of the tool 50. The purpose of this will be explained below.

The head 56 of the tool 50 is illustrated more clearly in Figure 5. The head 56 consists of two longitudinally-extending part-cylindrical tongues 60 formed by extensions of the cylindrical wall of the shaft 52. The tongues 60 are separated from one another by wedge-shaped gaps which are wider at the ends thereof remote from the handle 54 than at the ends 62 which are closer thereto. The closer ends 62 have a width w (see Figure 6) which is substantially the same as the width w of the end portion 24 of the retaining means 14 of the surgical anchor 10 (see Figure 2). These closer ends 62 are also shaped so as to be arcuate when viewed in the direction illustrated in Figure 7. Ideally, these closer ends 62 are either part-cylindrical or part-spherical, depending upon the shape of the outer side 24b of the end portion 24 of the retaining means 14 (see Figure 1).

The features of the retaining means 14 and the head 56 described above allow sufficient relative movement between the surgical anchor 10 and the tool 50 to provide the surgeon with adequate manoeuvrability and flexibility to ensure that the surgical anchor 10 can be introduced in to the blind end 32 of the bone tunnel 26 without serious difficulty even if the portions of the bone tunnel 26 in the tibia and femur become misaligned. The degrees of freedom provided by this arrangement are illustrated in Figures 6 and 7. Firstly, looking at Figure 6, it will be appreciated that the wedge-shaped gaps between the tongues 60 allow the retaining means 14 to rock through a pre-

determined angle with respect to the longitudinal axis of the shaft 52. The rocking movement is limited by the arms 22 abutting against the side walls of the tongues 60.

Figure 7 illustrates the cooperation of the arcuate side 24b of the end portion 24 and the end surfaces 62 of the wedge-shaped gaps closest to the handle 54. If the arcuate side 24b is part-cylindrical in shape, then the surfaces 62 will also be part-cylindrical. Similarly, if the arcuate side 24b is part-spherical, then the surfaces 62 will each be part-spherical. In any event, the cooperation of these surfaces will allow a small amount of rotation to take place between the shaft 52 and the retaining means 14. This provides the surgeon with another degree of freedom when introducing the surgical anchor 10 into the blind end 32 of a bone tunnel 26.

Figure 8 shows a combination of the surgical anchor 10 described above and the tool 50 described above immediately before use. In order to bring the combination into this configuration, the auxiliary ligament 34 is passed through the centre of the retaining means 14 of the surgical anchor 10 and doubled over to ensure that the ends of the ligament 34 are of substantially similar lengths. The ends of the ligament 34 are then passed through the hollow shaft 52 of the tool 50 and the retaining means 14 of the surgical anchor 10 are then brought into contact with the head 56 of the tool 50. Specifically, the side 24b of the end portion 24 is brought into abutting contact with the surfaces 62 forming the inner ends of the wedge-shaped gaps. The cylindrical tongues 60 extend beyond the end portion 24 of the retaining means 14 towards the surgical anchor 10 and substantially surround the ligament 34 in the area closest to the body portion 12 of the surgical anchor 10. The cylindrical portions 60 provide protection for the ligament 34 in that area.

Tension is applied to the ligament 34 in order to maintain the retaining means 14 in contact with the surfaces 62. However, limited movement between the retaining means 14 and the head 56 of the shaft 52 as illustrated in Figures 6 and 7 is permitted. If means are provided on the tool 50 for clamping or otherwise retaining the ligament 34 in this position, these means are then operated. The result is that, if the tool 50 is

rotated about the longitudinal axis of the shaft 52, the ligament 34 is rotated simultaneously and to the same extent. Rotation of the tool 50 and anchor 10 does not therefore result in any twisting of the ligament with respect to the anchor 10.

The surgeon is now able to introduce the surgical anchor 10 into the bone tunnel 26 from the tibial end thereof. The bone tunnel 26 ideally has a slightly larger diameter in those portions thereof in which the surgical anchor is not required to be retained. The surgical anchor 10 and shaft 52 therefore pass along the tunnel 26 in the tibia 28 without difficulty. At all times, the depth of penetration of the surgical anchor 10 and the head 56 is known by means of the graduations 58 located on the shaft 52. The surgical anchor 10 then has to be navigated across the gap between the tibia 28 and the femur 30 and into the mouth of the tunnel 26 in the femoral head. At this point, the articulation between the surgical anchor 10 and the head 56 is highly advantageous because the separate portions of the tunnel 26 can easily become misaligned during an operation. The ability of the surgical anchor 10 to rotate slightly in at least two directions assists the surgeon in locating the mouth of the tunnel 26 in the femur 30 and introducing the surgical anchor 10 therein. If required, a guide wire not illustrated can be introduced into the bone tunnel 26 from the femoral end thereof in order to assist the surgeon in locating the surgical anchor 10 in the mouth of the bone tunnel 26 in the femur 30. The guide wire will be introduced through the skin of the patient in the area above the knee and will extend at least as far as the gap between the tibia 28 and the femur 30. The surgeon will then locate the guide wire in the blind recess 20 in the nose portion 16 of the surgical anchor 10 and follow the guide wire along the bone tunnel 26, pushing the guide wire out of the bone tunnel 26 as the surgical anchor 10 advances according to known methods. Even though this technique requires a minor incision to be made in the patient's skin above the knee, a small incision heals quickly and normally leaves no permanent scar. The aim of the invention is therefore achieved equally with the use of a guide wire as without.

The blind end 32 of the bone tunnel 26 preferably has a reduced diameter over a length of tunnel at least as long as the body portion 12 of the surgical anchor 10. When

the body portion 12 reaches the portion of tunnel 26 with the reduced diameter, the surgeon will begin to rotate the handle 54 of the tool 50 so as to rotate the surgical anchor 10 therewith. The screw thread 18 then becomes securely attached to the wall of the bone tunnel 26. Because the bone tunnel 26 extends into the cortex of the femur 30, the surgical anchor 10 is securely fixed at the blind end 32 of the bone tunnel 26. As the surgeon rotates the tool 50, the ligament 32 is rotated as well. No twisting of the ligament 34 takes place with respect to the surgical anchor 10. When the surgical anchor 10 is firmly fixed at the blind end 32 of the bone tunnel 26, the tool 50 can be withdrawn, releasing the ligament clamping means first if necessary. The flat side 24a of the end portion 24 ensures that the ligament 34 does not "bunch up" towards the centre of the bone tunnel 26 thereby ensuring that the ligament 34 is maintained in contact with the walls of the tunnel 26 and thereby encouraging natural fixation. The free ends of the ligament 34 are secured by known fixation means, such as stapling, to the external surface of the tibia 28.

Although incisions are required in the area below the patient's knee joint to achieve the repair described above, the possibility of carrying out the operation without making any surgical incisions above the knee is highly advantageous because of the cosmetic advantages it achieves.

CLAIMS:

1. A surgical anchor for anchoring a prosthetic or soft tissue graft in a bone tunnel, the anchor comprising a body portion incorporating anchoring means for anchoring the body portion in the bone tunnel and retaining means for retaining the prosthetic or soft tissue graft on the anchor, wherein the anchoring means are capable of anchoring the body portion in the bone tunnel at or adjacent a blind end thereof.

2. A surgical anchor as claimed in Claim 1, wherein the anchoring means comprise at least one screw thread.

3. A surgical anchor as claimed in Claims 1 or 2, wherein the retaining means comprise a generally U-shaped eye portion extending from the body portion in the direction of the longitudinal axis thereof.

4. A surgical anchor as claimed in Claim 3, wherein the eye portion is closed.

5. A surgical anchor as claimed in Claim 4, wherein the eye portion comprises two longitudinally extending arms and a laterally extending end portion.

6. A surgical anchor as claimed in Claim 5, wherein the side of the laterally extending end portion facing the body portion is substantially flat and extends substantially perpendicular to the longitudinal axis thereof.

7. A surgical anchor as claimed in Claim 5 or 6, wherein the side of the laterally extending end portion remote from the body portion is arcuate.

8. A surgical anchor as claimed in any one of the preceding claims, wherein the body portion has means for receiving a guide wire located in the end of the body portion remote from the retaining means.

9. A surgical anchor as claimed in Claim 8, wherein the means for receiving a guide wire comprise a blind bore.

10. A surgical anchor substantially as hereinbefore described with reference to Figures 1 to 3 of the accompanying drawings.

11. A tool for fixing in place a surgical anchor according to any one of the preceding claims, comprising a shaft having a head adapted to cooperate with the anchor, and a handle, wherein the shaft has an inner cavity open at the head for receiving a prosthetic or soft tissue graft retained by the retaining means such that, when the tool is rotated about the longitudinal axis of the shaft so as to anchor the body portion of the surgical anchor in a bone tunnel, the prosthetic or soft tissue graft is rotated with the tool to prevent twisting.

12. A tool as claimed in Claim 11, wherein the inner cavity extends into the handle.

13. A tool as claimed in Claims 11 or 12, wherein the inner cavity has a second opening at or adjacent the handle to allow a portion of the prosthetic or soft tissue graft to remain outside the cavity when the tool is in use.

14. A tool as claimed in any one of Claims 11 to 13, further comprising means for preventing relative movement between the prosthetic or soft tissue graft and the tool when the tool is in use.

15. A tool as claimed in any one of Claims 11 to 14, wherein the head is adapted to cooperate with the retaining means of the anchor.

16. A tool as claimed in Claim 15, wherein the head is adapted to allow relative rotation between the head and the retaining means about two perpendicular axes lying in a plane perpendicular to the longitudinal axis of the shaft.

17. A tool as claimed in any one of Claims 11 to 16, wherein the head comprises two opposing part-cylindrical tongues separated by wedge-shaped gaps.

18. A tool as claimed in Claim 17, wherein each gap is widest at the end thereof furthest from the handle.

19. A tool as claimed in Claim 17 or 18, wherein the end of each wedge-shaped gap closest to the handle is arcuate.

20. A tool as claimed in Claim 19, wherein the end of each wedge-shaped gap is part-cylindrical or part-spherical.

21. A tool as claimed in any one of Claims 11 to 20, further comprising graduations arranged on the shaft.

22. A tool substantially as hereinbefore described with reference to Figures 4 to 8 of the accompanying drawings.

23. The combination of a tool as claimed in any one of Claims 11 to 22 and at least one surgical anchor as claimed in any one of Claims 1 to 10.

The Patent Office

Application No: GB 9608340.7
Claims searched: 1-10

Examiner: Dr J Houlihan
Date of search: 19 July 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RAM, RESA)

Int Cl (Ed.6): A61B 17/03, A61F 2/08

Other:

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	EP 0619982 A2	(MITEK SURG. PROD.) page 5 lines 54-58; page 8 lines 50-51; Figures 2 & 3	1, 2, 3, 5, 6, 7 & 8
X	EP 611557 A2	(SMITH & NEPHEW) column 9 line 53-column 10 line 8; column 10 lines 32-35; Figure 5	1 & 2
X	WO 95/22930 A1	(ORTHOPAEDIC BIOSYSTEMS) page 15 lines 23-25; page 18 lines 14-19; page 20 lines 13-17; Figure 7	1-4 & 7
X	US 5443482	(STONE K R) column 3 lines 60-64; column 7 lines 34-37	1-7
X	US 5417712	(WHITTAKER G R *et. al.)* column 6 lines 49-52; column 7 lines 27-44; Figures 1, 10, 19, 21A, 22, 25, 28 & 42	1 & 3-7
X	US 5411506	(GOBLE E M *et. al.)* column 4 lines 29-34; Figures 1-4	1-6
X	US 5372604	(TROTT A F) column 8 lines 26-40; Figures 1, 11 & 12	1, 3-5 & 7

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

The Patent Office

Application No: GB 9608340.7 **Examiner:** Dr J Houlihan
Claims searched: 1-10 **Date of search:** 19 July 1996

Category	Identity of document and relevant passage		Relevant to claims
X	US 5207679	(LEHMANN K L) column 8 lines 27-48; Figures 1 & 2	1, 3-6 & 8
X	US 5152790	(ROSENBERG T D *et.al.)* column 3 lines 20-37; Figures 3 & 4	1-4
X	US 4870957	(GOBLE E M *et. al.*) column 4 lines 25-29; Figures 1-3	1-6 & 8

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.